

## **REMARKS**

### **I. Status of Claims**

By this Response, Applicants have amended claim 13, cancelled claims 1-8 and 10, and added new claims 14-18. In a Response to a Restriction Requirement dated December 7, 2009, Applicants provisionally elected claims drawn to a "method for prophylaxis of migraine comprising administering a selective dual antagonist," as in claim 9. New claims 14-18 read on that elected invention. Thus, claims 9 and 11-14 are present in the application and pending on the merits.

### **II. Election of Species**

The Office has issued a supplemental species election requirement. The Office states that "Claims 9 and 11-13 are generic to the...[s]tructure of the selective dual antagonist for the 5-HT<sub>2B</sub> and 5-HT<sub>7</sub> receptors," and requests that Applicants "specify a single chemical structure species for the selective dual antagonist for the 5-HT<sub>2B</sub> and 5-HT<sub>7</sub> receptors." Office Action at 2.

Applicants respectfully submit that, in accordance with the present specification, the "dual antagonist for the 5-HT<sub>2B</sub> and 5-HT<sub>7</sub> receptors," as recited in claim 9, may comprise, in one embodiment, a single compound having both antagonistic actions and, in another embodiment, two different compounds, each having one of the antagonistic actions:

In the present invention, a "dual antagonist for the 5-HT<sub>2B</sub> and 5-HT<sub>7</sub> receptors" means a drug which acts antagonistically with serotonin to reduce simultaneously the effect mediated by both of the 5-HT<sub>2B</sub> and 5-HT<sub>7</sub> receptors, and includes pharmaceutical preparations containing as an active ingredient a compound having both of the antagonistic actions, and pharmaceutical preparations containing two active ingredients, i.e., a compound having a 5-HT<sub>2B</sub>

receptor antagonistic action and a compound having a 5-HT<sub>7</sub> receptor antagonistic action.

See page 7, line 22 to page 8, line 2. This distinction is also made clear by the explicit recitation of claims 11 and 12. Accordingly, to be fully responsive to the Office's requirement for election of species, Applicants provisionally elect structures corresponding to both scenarios, as described below.

For claims readable on a selective dual antagonist comprising a single compound with both 5-HT<sub>2B</sub> and 5-HT<sub>7</sub> receptor activity, Applicants provisionally elect to prosecute the compound of preparation 3, page 32 of the as-filed specification:

- N-(diaminomethylene)-9-hydroxy-9H-fluorene-2-carboxamide.

Claims readable on this species are claims 9 and 12-18.

For claims readable on a selective dual antagonist comprising two different compounds, each having one of the antagonistic actions, Applicants provisionally elect to prosecute the compounds of preparation 111, page 35 of the as-filed specification:

- 2-amino-4-(4-fluoronaphtho-1-yl)-6-isopropylpyrimidine (RS-127445) as a compound having 5-HT<sub>2B</sub> antagonistic activity; and
- (R)-3-(2-(4-methylpiperidine-1-yl)ethyl)pyrrolidine-1-sulfonylphenol (SB-269970) as a compound having 5-HT<sub>7</sub> antagonistic activity.

Claims readable on these species include claims 9, 11, and 13-18.

This election is not intended to limit the scope of the claims and Applicants understand that, upon allowance of the scope of the restricted claims drawn to the elected species, the examination of the claims will be expanded to include consideration of full scope of the generic claims.

### **III. Amendment to Specification**

Applicants have amended the paragraph appearing on page 8, line 25 to page 9, line 4 of the specification to insert the term “5-HT<sub>3</sub>” on page 9 at line 2, which term was inadvertently omitted from the English translation of the PCT application due to a translation error. This term is fully supported elsewhere in the as-filed specification, for example, by at least page 9, line 4. Additionally, the inclusion of this term is apparent at page 7, line 4 of the original priority document JP 2005-002946. Therefore, Applicants request that the amendment be entered without objection.

### **IV. Amendments to the Claims**

Amended claim 13 and new claims 16, 17, and 18 recite that the “Ki or IC<sub>50</sub> values” for the 5-HT<sub>2B</sub> and 5-HT<sub>7</sub> receptors are “one-hundredth or less” or “one-tenth or less” than those of other receptors, including  $\alpha_1$ , M<sub>1</sub>, D<sub>2</sub>, 5-HT<sub>1A</sub>, 5-HT<sub>1B</sub>, 5-HT<sub>2A</sub>, 5-HT<sub>2C</sub>, 5-HT<sub>3</sub>, 5-HT<sub>4</sub> and 5-HT<sub>6</sub> receptors. New claims 14 and 15 recite that the binding affinities for the 5-HT<sub>2B</sub> and 5-HT<sub>7</sub> receptors are higher than those of other specified receptors. This amendment, and these new claims are fully supported in the original specification by at least page 8, line 3 to page 9, line 25. Accordingly, Applicants request that the claims be entered without rejection or objection.

### **V. Conclusion**

If the Examiner believes that a telephone conversation might advance the prosecution of this application, the Examiner is cordially invited to call Applicants' undersigned attorney at (404) 653-6430.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account 06-0916.

Respectfully submitted,

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